Contents Update Record

October 2017 (v2.0)
This document has been updated following formal review of the Clinical Trial Access Quality Performance Indicator (QPI) which took place following analysis of year 3 of the clinical trial access QPI data.

The QPI has been updated along with sections 1 – 12 and the appendices. As a result of these changes, the contents page and page numbering differ from the earlier version of this document.

Please note that this version of the Clinical Trial Access QPI document applies to cases consented for clinical trials from 1st January 2017 onwards.
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1. National Cancer Quality Programme

Better Cancer: Ambition and Action (2016)\(^1\) details a commitment to delivering the national cancer quality programme across NHSScotland, with a recognised need for national cancer QPIs to support a culture of continuous quality improvement. Addressing variation in the quality of cancer services is pivotal to delivering improvements in quality of care. This is best achieved if there is consensus and clear indicators for what good cancer care looks like.

Small sets of cancer specific outcome focused, evidence based indicators are in place for 18 different tumour types. These are underpinned by patient experience QPIs that are applicable to all, irrespective of tumour type. These QPIs ensure that activity is focused on those areas that are most important in terms of improving survival and individual care experience whilst reducing variation and supporting the most effective and efficient delivery of care for people with cancer. QPIs are kept under regular review and are responsive to changes in clinical practice and emerging evidence.

A programme to review and update the QPIs in line with evolving evidence is in place as well as a robust mechanism by which additional QPIs will be developed over the coming years.

1.1 Quality Assurance and Continuous Quality Improvement

The ultimate aim of the programme is to develop a framework, and foster a culture of, continuous quality improvement, whereby real time data is reviewed regularly at an individual Multi Disciplinary Team (MDT)/Unit level and findings actioned to deliver continual improvements in the quality of cancer care. This will be underpinned and supported by a programme of regional and national comparative reporting and review.

NHS Boards will be required to report against QPIs as part of a mandatory, publicly reported, programme at a national level. A rolling programme of reporting is in place, with approximately three national tumour specific reports published annually. National reports include comparative reporting of performance against QPIs at MDT/Unit level across NHSScotland, trend analysis and survival. This approach helps to overcome existing issues relating to the reporting of small volumes in any one year.

In the intervening years tumour specific QPIs are monitored on an annual basis through established Regional Cancer Networks and local governance processes, with analysed data submitted to Information Services Division (ISD) for inclusion in subsequent national reports. This approach ensures that timely action is taken in response to any issues that may be identified through comparative reporting and systematic review.

2. Quality Performance Indicator Development Process

The QPI development process was designed to ensure that indicators are developed in an open, transparent and timely way. The development process can be found in appendix 1.

A short life working group (SLWG) established by the National Cancer Quality Steering Group (NCQSG) was convened in June 2013, chaired by Dr Hilary Dobson (Chair – National Cancer Quality Steering Group). Membership of this group included representatives from all four Scottish Cancer Research Networks (SCRN) and can be found in appendix 2.
3. QPI Formal Review Process

As part of the National Cancer Quality Programme a systematic national review process has been developed, whereby all tumour specific QPIs published are subject to formal review following 3 years analysis of comparative QPI data.

Formal review of the Clinical Trial Access QPI was undertaken in April 2017. A Formal Review Group was convened, chaired by Mr Gren Oades (Regional Clinical Lead, Urological Cancers MCN, West of Scotland Cancer Network). Membership of this group included Clinical Leads and Network Managers from the regional Scottish Cancer Research Networks (SCRN). Membership of this group can be found in appendix 3.

The formal review process is clinically driven with comments sought from specialty specific representatives in each of the Regional Cancer Networks for discussion at the initial meeting. This review builds on existing evidence using expert clinical opinion to identify where new evidence is available.

During formal review QPIs may be removed and replaced with new QPIs. Triggers for doing so include significant change to clinical practice, targets being consistently met by all Boards, and publication of new evidence.

Any new QPIs have been developed in line with the following criteria:

- **Overall importance** – does the indicator address an area of clinical importance that would significantly impact on the quality and outcome of care delivered?
- **Evidence based** – is the indicator based on high quality clinical evidence?
- **Measurability** – is the indicator measurable i.e. are there explicit requirements for data measurement and are the required data items accessible and available for collection?

The revised Clinical Trial Access QPI was made available on the Scottish Government Consultation Hub in July / August 2017 as part of a wide clinical and public engagement exercise.

During the engagement period, clinical and management colleagues from across NHSScotland, patients and the wider public were given the opportunity to influence the revised Clinical Trial Access QPI. Following the engagement period all comments and responses received were reviewed by the Formal Review Group and used to produce and refine the final indicator (section 7).

4. Format of the Quality Performance Indicators

QPIs are designed to be clear and measurable, based on sound clinical evidence whilst also taking into account other recognised standards and guidelines.

- Each QPI has a **short title** which will be utilised in reports as well as a fuller **description** which explains exactly what the indicator is measuring.
- This is followed by a brief overview of the **evidence base and rationale** which explains why the development of this indicator was important.
- The measurability **specifications** are then detailed; these highlight how the indicator will actually be measured in practice to allow for comparison across NHS Scotland.
• Finally a target is indicated, this dictates the level which each unit should be aiming to achieve against each indicator.

In order to ensure that the chosen target level is the most appropriate and drives continuous quality improvement as intended it will be kept under review and revised as necessary, when baseline data or further evidence becomes available.

Rather than utilising multiple exclusions, a tolerance level has been built into the QPI. It is very difficult to accurately measure patient choice, as well as eligibility for trials due to co-morbidities and patient fitness levels, therefore the target level has been set to account for these factors. In addition, there may be a lack of available trials recruiting during the specific period of reporting, or studies may be available that do not meet the approval criteria for inclusion noted in section 6.

5. Definitions

In order to ensure appropriate and nationally comparative measurement against the QPI developed it is of utmost importance to agree consistent definitions of the various types of studies considered in the QPI. The following different types of studies are all included within measurement of the QPI.

<table>
<thead>
<tr>
<th>Research</th>
<th>Research can be defined as the attempt to derive generalisable (i.e. of value to others in a similar situation) new knowledge by addressing clearly defined questions with systematic and rigorous methods. This excludes: audit; needs assessments; quality improvement and other local service evaluations. It also excludes routine banking of biological samples or data except where this activity is integral to a self-contained research project designed to test a clear hypothesis.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interventional Clinical Trial</td>
<td>A clinical study in which participants are assigned to receive one or more interventions (or no intervention) so that researchers can evaluate the effects of the interventions on biomedical or health-related outcomes. The assignments are determined by the study protocol. Participants may receive diagnostic, therapeutic, or other types of interventions.</td>
</tr>
<tr>
<td>Translational Research</td>
<td>A term used to describe the process by which the results of research done in the laboratory are used to develop new ways to diagnose and treat disease. The development of the breast cancer drug trastuzumab (Herceptin) is an example for this kind of research. Researchers derived knowledge about the function and presence of a specific gene (HER2) from laboratory studies. This information was then used to develop trastuzumab (Herceptin), which is an effective treatment of cancerous cells in patients whose cancers overexpress the protein coded by this gene.</td>
</tr>
<tr>
<td>Observational Study</td>
<td>A type of study in which individuals are observed or certain outcomes are measured. No attempt is made to affect the outcome (for example, no treatment is given).</td>
</tr>
</tbody>
</table>
6. Inclusion Criteria
In order to ensure the most complete and accurate data is available for national comparative reporting, the Clinical Trials QPI Formal Review Group have agreed specific inclusion criteria for the measurement of this QPI:

- The Clinical Trial and Research Study Access QPI will be measured for patients with a confirmed cancer diagnosis that aligns to those tumour types with nationally agreed QPIs.

- Clinical trials are either commercially sponsored studies or non-commercial studies (as defined as eligible by the National Institute for Health Research (NIHR) or the Chief Scientist Office (CSO)) where patients have given informed consent to participate. This will include interventional trials, translational research and observational studies involving patients. Further information on non-commercial eligibility is detailed in appendix 4.
7. Quality Performance Indicator for Clinical Trial and Research Study Access

<table>
<thead>
<tr>
<th>QPI Title:</th>
<th>All patients should be considered for participation in available clinical trials / research studies, wherever eligible.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Description:</td>
<td>Proportion of patients diagnosed with [insert tumour type] cancer who are consented* for a clinical trial / research study.</td>
</tr>
<tr>
<td>Rationale and Evidence:</td>
<td>Clinical trials are necessary to demonstrate the efficacy of new therapies and other interventions6. Evidence suggests improved patient outcomes when hospitals are actively recruiting patients into clinical trials7. Clinicians are therefore encouraged to enter patients into well-designed trials and to collect longer-term follow-up data. High accrual activity into clinical trials is used as a goal of an exemplary clinical research site. The measurement of this QPI focuses on those patients who have consented in order to reflect the intent to join a clinical trial and demonstrate the commitment to recruit patients. Often patients can be prevented from enrolling within a trial due to stratification of studies and precise inclusion criteria identified during the screening process.</td>
</tr>
<tr>
<td>Specifications:</td>
<td>Numerator: Number of patients diagnosed with [insert tumour type] cancer consented for a clinical trial / research study. Denominator: All patients diagnosed with [insert tumour type] cancer. Exclusions: • No exclusions.</td>
</tr>
<tr>
<td>Target:</td>
<td>15%</td>
</tr>
</tbody>
</table>

*Consented is defined as patients who have given consent to participate in a clinical trial / research study subject to study specific screening for eligibility.

Please note: The denominator for this QPI is identified by using a 5 year average of Scottish Cancer Registry data (methodology is described in section 8).
8. Methodology

The clinical trials QPI will be measured utilising SCRN data and ISD incidence data, as is the methodology currently utilised by the Chief Scientist Office (CSO) and NCRI. The principal benefit of this approach is that this data is already collected utilising a robust mechanism. At present a 'clinical trial' data item is contained within all tumour specific datasets, however in order to avoid any duplication of effort, and focus resources appropriately, SCRN data is the preferred option. In addition, this data item may also be used to identify particular subgroups of patients for measurement of other tumour specific QPIs.

Utilising SCRN data allows for comparison with CSO published data and ensures capture of all clinical trials activity, not solely first line treatment trials, as contained in the clinical audit data. Given that a significant proportion of clinical trials are for relapsed disease this is felt to be particularly important in driving quality improvement. This methodology utilises incidence as a proxy for all patients with cancer. This may slightly over, or underestimate, performance levels, however this is an established approach currently utilised by NHSScotland.

9. Reporting

The Clinical Trial and Research Study Access QPI will be reported alongside tumour specific QPIs for the most recent calendar year. The patient cohort used to measure the Clinical Trial Access QPI is different to that of the tumour specific QPIs due to the methodology utilised and it is therefore not necessary to use an identical timeframe for reporting. In order to avoid multiple data requests to SCRN for different tumour groups it is considered most appropriate to align the tumour sites to one calendar year for reporting purposes.

Additional information will be reported alongside the QPI in order to provide further context for each tumour site. This will include the following:

- Details of all clinical trials open to recruitment in each cancer centre during the audit period.
- Percentage of patients enrolled in clinical trials.

10. Governance and Scrutiny

A national and regional governance framework to assure the quality of cancer services in NHSScotland has been developed; key roles and responsibilities within this are set out below. Appendices 5 and 6 provide an overview of these governance arrangements diagrammatically. The importance of ensuring robust local governance processes are in place is recognised and it is essential that NHS Boards ensure that cancer clinical audit is fully embedded within established processes.

10.1 National

- Scottish Cancer Taskforce
  - Accountable for overall national cancer quality programme and overseeing the quality of cancer care across NHSScotland.
  - Advising Scottish Government Health and Social Care Directorate (SGHSCD) if escalation required.
• Healthcare Improvement Scotland
  ▪ Proportionate scrutiny of performance.
  ▪ Support performance improvement.
  ▪ Quality assurance: ensure robust action plans are in place and being progressed via regions/Boards to address any issues identified.

• Information Services Division (ISD)
  ▪ Publish national comparative report on tumour specific QPIs and survival for 3 tumour types per annum and specified generic QPIs as part of the rolling programme of reporting.

10.2 Regional – Regional Cancer Networks

• Annual regional comparative analysis and reporting against tumour specific QPIs.
• Support national comparative reporting of specified generic QPIs.
• Identify and share good practice.
• In conjunction with constituent NHS Boards identify regional and local actions required to develop an action plan to address regional issues identified.
• Review and monitoring of progress against agreed actions.
• Provide assurance to NHS Board Chief Executive Officers and Scottish Cancer Taskforce that any issues identified have been adequately and timeously progressed.

10.3 Local – NHS Boards

• Collect and submit data for regional comparative analysis and reporting in line with agreed measurability and reporting schedule (generic and tumour specific QPIs).
• Utilise local governance structures to review performance, develop local action plans and monitor delivery.
• Demonstrate continual improvements in quality of care through on-going review, analysis and feedback of clinical audit data at an individual multidisciplinary team (MDT) or unit level.
11. References


12. Abbreviations

CSO  Chief Scientist Office
ISD  Information Services Division
MDT  Multi - Disciplinary Team
NCQSG  National Cancer Quality Steering Group
NCRI  National Cancer Research Institute
NRS  NHS Research Scotland
QPIs  Quality Performance Indicators
RCAGs  Regional Cancer Advisory Groups
SCRN  Scottish Cancer Research Network
SGHSCD  Scottish Government Health and Social Care Directorate
SLWG  Short Life Working Group
13. Appendices

Appendix 1 – Clinical Trial Access QPI Development Process

Preparatory Work and Scoping

The National Cancer QPI Development Programme commenced in May 2010. At the outset, it was apparent that various issues were common to all cancer types. These areas were agreed by the National Cancer Quality Steering Group (NCQSG) to be: Multi-Disciplinary Team Meeting; Clinical Trial Access; and Patient Experience.

A generic QPI regarding Clinical Trial Access was developed by the NCQSG, based upon the NHS Quality Improvement Scotland Standards for the Management of Core Cancer Services\(^3\), published in 2008. Following discussion at the NCQSG, further development and consultation was undertaken, principally with the Scottish Cancer Research Networks.

Indicator Development

The Clinical Trials short life working group (SLWG) defined an evidence based, measurable indicator with a clear focus on improving the quality and outcome of care provided.

The following criteria was utilised when developing the QPI:

- **Overall importance** – does the indicator address an area of clinical importance that would significantly impact on the quality and outcome of care delivered?

- **Evidence based** – is the indicator based on high quality clinical evidence?

- **Measurability** – is the indicator measurable, that is, are there explicit requirements for data measurement and are the required data items accessible and available for collection?

Engagement Process

The Clinical Trial Access QPI was included as part of the Clinical Trial Quality Performance Indicator Engagement Document which was made available on the Scottish Government website in January 2014, as part of a wide clinical and public engagement exercise.

During the engagement period clinical and management colleagues from across NHSScotland, patients and the wider public were given the opportunity to influence the development of the Clinical Trial Access QPI. Several different methods of engagement were utilised:

**Professional groups, health service staff, voluntary organisations and individuals:**

- Wide circulation of the draft documentation for comment and feedback.

**Patient representative groups:**

- Organised patient focus group sessions were held.

Following the engagement period all comments and responses received were reviewed by the SLWG and used to produce and refine the final indicator.
### Appendix 2 – Membership of the Clinical Trial Short Life Working Group (2014)

<table>
<thead>
<tr>
<th>Name</th>
<th>Designation</th>
<th>Organisation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shelagh Bonner-Shand</td>
<td>Manager</td>
<td>SCRN North</td>
</tr>
<tr>
<td>Dorothy Boyle</td>
<td>Manager</td>
<td>SCRN South East</td>
</tr>
<tr>
<td>Chloe Cowan</td>
<td>Manager</td>
<td>SCRN West</td>
</tr>
<tr>
<td>Hilary Dobson (CHAIR)</td>
<td>Chair - National Cancer Quality Steering Group</td>
<td></td>
</tr>
<tr>
<td>David Dunlop</td>
<td>Clinical Lead</td>
<td>SCRN West</td>
</tr>
<tr>
<td>Charlie Gourlay</td>
<td>Clinical Lead</td>
<td>SCRN South East</td>
</tr>
<tr>
<td>Kelly Macdonald</td>
<td>Project Manager</td>
<td>National Cancer QPI Development Programme</td>
</tr>
<tr>
<td>Marianne Nicolson</td>
<td>Clinical Lead</td>
<td>SCRN North</td>
</tr>
<tr>
<td>Iona Scott</td>
<td>Project Manager</td>
<td>National Cancer QPI Development Programme</td>
</tr>
<tr>
<td>Alistair Thompson</td>
<td>Clinical Lead</td>
<td>SCRN East</td>
</tr>
<tr>
<td>Charles Weller</td>
<td>Manager</td>
<td>SCRN East</td>
</tr>
</tbody>
</table>
### Appendix 3 – Clinical Trial QPI Formal Review Group Membership (2017)

<table>
<thead>
<tr>
<th>Name</th>
<th>Designation</th>
<th>Organisation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gren Oades (Chair)</td>
<td>Regional Clinical Lead, Urological Cancers MCN</td>
<td>WoSCAN</td>
</tr>
<tr>
<td>Karen Bell</td>
<td>Acting Network Manager</td>
<td>SCRN West</td>
</tr>
<tr>
<td>Dorothy Boyle</td>
<td>Network Manager</td>
<td>SCRN East</td>
</tr>
<tr>
<td>Ewan Brown</td>
<td>Clinical Lead</td>
<td>SCRN East</td>
</tr>
<tr>
<td>Lorna Bruce</td>
<td>Audit Manager</td>
<td>SCAN</td>
</tr>
<tr>
<td>David Cameron</td>
<td>Scottish Cancer Research Champion</td>
<td>SCAN</td>
</tr>
<tr>
<td>Louise Devlin</td>
<td>Lead Cancer Trials Nurse</td>
<td>WoSCAN</td>
</tr>
<tr>
<td>Jen Doherty</td>
<td>Project Co-ordinator</td>
<td>National Cancer Quality Programme</td>
</tr>
<tr>
<td>Iain MacPherson</td>
<td>Clinical Lead</td>
<td>SCRN West</td>
</tr>
<tr>
<td>Marianne Nicolson</td>
<td>Clinical Lead</td>
<td>SCRN North</td>
</tr>
<tr>
<td>Kirsty Shearer</td>
<td>Network Manager</td>
<td>SCRN North</td>
</tr>
<tr>
<td>Lorraine Stirling</td>
<td>Project Officer</td>
<td>WoSCAN</td>
</tr>
<tr>
<td>Christine Urquhart</td>
<td>Audit Manager</td>
<td>NOSCAN</td>
</tr>
</tbody>
</table>
Appendix 4 – Eligibility for NHS Research Scotland (NRS) Support

NRS funds can be used to support the following:

1. Non-commercial studies funded by a CSO eligible funder (see list in Annex 2)

2. Studies which are not on the CSO eligible funder list, but which are either led from England, or are led from Scotland with participating English sites, and are considered eligible and supported by the NIHR CRN, either by means of:
   - entry on the NIHR non-commercial partner list
   - self-declaration as an NIHR non-commercial partner

Further information can be found here: https://www.nihr.ac.uk/funding-and-support/study-support-service/Information-for-research-funders.htm

3. Studies which are not on the CSO eligible funder list, but which are either led from England, or are led from Scotland with participating English sites, and have successfully applied through the NIHR non-commercial adoption process. This applies to:
   - Investigator initiated trials (i.e. commercial collaborative research)
   - Studies funded by overseas Governments
   - Studies funded by overseas charities

4. Studies led from and active only in Scotland which have successfully applied through the NIHR non-commercial adoption process (the Standard Operating Procedure for this process attached as Annex 3).

5. Studies which are not on the CSO eligible funder list, but are led from either Wales or NI with Scottish sites, or are Scottish-led with sites in NI or Wales, and are considered eligible for support by the devolved administrations in NI and Wales may be also eligible for CSO support, subject to confirmation from CSO.

Projects must meet the CSO definition of research to be supportable – e.g. travel awards, equipment grants, establishment of tissue banks and databases etc. are not eligible.

Studies in the categories above can be included in the Project return for NRS Researcher Support and recruitment will count towards both the Recruitment Premium element of Researcher Support and activity based NRS Service Support. Exceptionally, CSO reserves the right to extend eligibility to particular projects and/or initiatives in relation to particular policy areas.

Full information on NRS Funding Guidance can be found here:
Annexes

Annexes and electronic versions of this document can be found at the following location: http://www.nhsresearchscotland.org.uk/education-and-funding/funding-for-nhs-research-infrastructure

Annex 1 – Guidance for the production of the annual project return

Annex 2 – Eligible funder list

Annex 3 – Standard operating procedure for adoption of Scotland-only studies

Annex 4 – Recruitment Premium – Policy on stratification of studies
Appendix 5 – Yearly National Governance Process & Improvement Framework for Cancer Care

This process is underpinned by the annual regional reporting and governance framework (see appendix 6).

1. National QPI Development Stage
   - QPIs developed by QPI development groups, which include representation from Regional Cancer Networks, Healthcare Improvement Scotland, ISD, patient representatives and the Cancer Coalition.

2. Data Analysis Stage:
   - NHS Boards and Regional Cancer Advisory Groups (RCAGs)* collect data and analyse on yearly basis using nationally agreed measurability criteria and produce action plans to address areas of variance, see appendix 6.
   - Submit yearly reports to ISD for collation and publication every 3 years.
   - National comparative report approved by NHS Boards and RCAGs.
   - ISD produce comparative, publicly available, national report consisting of trend analysis of 3 years data and survival analysis.

3. Expert Review Group Stage (for 3 tumour types per year):
   - Expert group, hosted by Healthcare Improvement Scotland, review comparative national results.
   - Write to RCAGs highlighting areas of good practice and variances.
   - Where required NHS Boards requested to submit improvement plans for any outstanding unresolved issues with timescales for improvement to expert group.
   - Improvement plans ratified by expert group and Scottish Cancer Taskforce.

4. Improvement Support Stage:
   - Where required Healthcare Improvement Scotland provide expertise on improvement methodologies and support.

5. Monitoring Stage:
   - RCAGs work with Boards to progress outstanding actions, monitor improvement plans and submit progress report to Healthcare Improvement Scotland.
   - Healthcare Improvement Scotland report to Scottish Cancer Taskforce as to whether progress is acceptable.

6. Escalation Stage:
   - If progress not acceptable, Healthcare Improvement Scotland will visit the service concerned and work with the RCAG and Board to address issues.
   - Report submitted to Scottish Cancer Taskforce and escalation with a proposal to take forward to Scottish Government Health Department.

*In the South and East of Scotland Cancer Network (SCAN) the Regional Cancer Planning Group is the equivalent group to Regional Cancer Advisory Group (RCAG).
Appendix 6 – Regional Annual Governance Process and Improvement Framework for Cancer Care

1. Regional QPI Implementation Stage:
   - National cancer QPIs and associated national minimum core dataset and measurability specifications, developed by QPI development groups.
   - Regional implementation of nationally agreed dataset to enable reporting of QPIs.

2. Data Analysis Stage:
   - NHS Boards collect data and data is analysed on a yearly basis using nationally agreed measurability criteria at local/ regional level.
   - Data/results validated by Boards and annual regional comparative report produced by Regional Networks.
   - Areas of best practice and variance across the region highlighted.
   - Yearly regional reports submitted to ISD for collation and presentation in national report every 3 years.

3. Regional Performance Review Stage:
   - RCAGs* review regional comparative report.
   - Regional or local NHS Board action plans to address areas of variance developed.
   - Appropriate leads identified to progress each action.
   - Action plans ratified by RCAGs.

4. Monitoring Stage:
   - Where required, NHS Boards monitor progress with action plans and submit progress reports to RCAGs.
   - RCAGs review and monitor regional improvement.

5. Improvement Support Stage:
   - Where required Healthcare Improvement Scotland maybe requested to provide expertise to NHS Boards/RCAGs on improvement methodologies and support.

6. Escalation Stage:
   - If progress not acceptable, RCAGs will escalate any issues to relevant Board Chief Executives. If progress remains unacceptable RCAGs will escalate any relevant issues to Healthcare Improvement Scotland.